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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,109	12/02/1999	MARK R. PRAUSNITZ	BVTP-P01-539	2183
28120	7590	01/27/2004	EXAMINER	
ROPER & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			KREMER, MATTHEW J	
			ART UNIT	PAPER NUMBER
			3736	18

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/453,109

Applicant(s)

PRAUSNITZ ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-26, 31-35, 37 and 42-45 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 27, 29, 30, 36, 38-41 and 46 is/are rejected.
- 7) ☒ Claim(s) 5, 7-14 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1-4, 6, 27, 29-30, 36, 38-41, and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 9 of U.S. Patent No. 6,503,231 to Prausnitz et al. ('231) in view of Japanese Patent Application Publication JP07132119A to Yoshihiko (cited by Applicant). Claim 1 of '231 claims a device for transport of material or energy across biological barriers comprising: a plurality of hollow microneedles having a length between 100 microns and 1 mm; a substrate to which the microneedles are attached or integrally formed; the microneedles extending at an angle from the substrate; and wherein each microneedle has a shaft, a portion of which comprises one or more substantially annular bores or channels therethrough and which has a width between about 1 microns and 100 microns. Claim 1 of '231 does not teach a collection chamber

which is selectably in fluid communication with the base end of the microneedle. Claim 1 of '231 teaches that the device is used to transport material or energy across biological barriers. Yoshihiko discloses a blood-collecting device that includes a substrate 1 with a plurality of microneedles 11 and a collection chamber (where the number 12 is located). Such an application of the microneedles would fall under the scope of a device for the transport of material or energy across biological barriers. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of '231 as a blood collection device as disclosed by Yoshihiko since claim 1 of '231 teaches that the device is used for the transport of material or energy across biological barriers and Yoshihiko teaches one such application. Claim 1 of '231 claims that the needles extend at an angle from the substrate. Claim 1 of '231 does not claim what that angle is. Yoshihiko teaches needles that are perpendicular to the substrate. (Fig. 2 of Yoshihiko). Such an angle would fall within the scope of "at an angle" as claimed in '231. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of '231 so that the needles would be perpendicular to the substrate as disclosed by Yoshihiko since claim 1 of '231 teaches that the needles extend from the substrate at an angle and Yoshihiko teaches one such angle. In regard to claims 2-4 and 6, a means for inducing flow is disclosed. (paragraph 0009 of Yoshihiko). The membrane 12 is deformed when heat is generated from the micro-heater 3, which increases the volume of the collection chamber. In claims 3 and 29, the blood is collected using a negative pressure in the collection chamber. (lines 9-10 of the

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constitution of Yoshihiko). In regard to claim 30, the device sucks up blood, which inherently includes glucose, cholesterol, and hemoglobin. (paragraph 0007 of Yoshihiko). In regard to claim 36, the device is applied to the skin surface of a human being. (paragraph 0021 of Yoshihiko). In regard to claim 38, the needle comprises metal. (claim 6 of '231). In regard to claim 39, the microneedle consists essentially of a metal. (claim 9 of '231). In regard to claim 46, claim 1 of '231 claims that the shafts have widths of 1-100 microns and it is obvious to one with ordinary skill in the art that any diameter in that range would fall within the scope of the claims.

Response to Arguments

3. Applicant's arguments filed 11/17/2003 have been fully considered but they are not persuasive. The Applicant's mere offer to file a terminal disclaimer does not overcome the double patenting rejections. The double patenting rejections will be withdrawn upon the filing of an acceptable terminal disclaimer.

Allowable Subject Matter

4. Claims 5, 7-14 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 15-26,31-35,37 and 42-45 are allowed.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736



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